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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/588,314	06/06/2000	Brian S. Hooker	059440/0128	9635

7590 09/07/2004

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EXAMINER

ASHEN, JON BENJAMIN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/588,314

Applicant(s)

HOOKE ET AL.

Examiner

Jon B. Ashen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,12,18-22 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) 24-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10,12,18-22 and 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 10, 2004 has been entered.

Status of the Application

2. Claims 1-10, 12, 18-22 and 24-31 are pending in this application. Applicant cancelled claims 13, 15 and 23 in the communication filed June 10, 2004. Newly submitted claims 24-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly presented claims 24-31 are drawn a compound, the polynucleotide sequence of claim 24, and to compounds and compositions comprising said compound that are an expression vector (claim 25), a plant cell, plant or seed (claims 26-28 respectively), a plant extract comprising full length human coagulation factor VIII (claim 29), a plant cell or a plant expressing full length human coagulation factor VIII.

In the instant case, the inventions of newly presented claims 24-31 is distinct from the originally presented invention of claims 1-10, 12, 18-22 because of the following reasons. The inventions of the newly presented claims 24-31 (that are compounds and compositions) and the invention as originally presented in claims 1-10, 12, 18-22 (that are methods) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product that would be a hybridization assay to determine tissue or cell specific gene expression of human coagulation factor VIII. Accordingly, claims 24-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-10, 12 and 18-22 are maintained as rejected and claims 24-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record set forth in the prior Office action, mailed 05/06/2003. This is a written description rejection.

5. Claims 1-10, 12 and 18-22 are maintained as rejected and claims 24-31 are rejected under 35 U.S.C. 112, first paragraph, as not fully enabled by the specification for the reasons set forth in the prior Office action, mailed 05/06/2003.

Response to Arguments

6. In regards to the written description rejection claims 1-10, 12 and 18-22, the rejection of record considers that claims directed to the full length gene still include variant sequences and modified sequences not described in the specification. Applicant has argued that the amendment of claims 1 and 6 (and claims 2-5 and 7-10 which depend from claims 1 and 6, respectively), filed 6/10/2004, limits the scope of these claims to the allowable subject matter. This argument has not been found to be persuasive. Applicant's attention is drawn to the prior Advisory Action of 6/4/2004 that sets forth that no claims have been found allowable in the instant application. Therefore, the rejection of record over claims 1-10, 12 and 18-22 is maintained for the reasons discussed in the rejection mailed 12-19-2004, because claims directed to the full length gene would still encompass modified versions of the full length sequence not

described in the specification as filed. For example, the claims would still encompass mutant sequences, allelic variants, and other undescribed modified, variant sequences, a representative number of modified sequences were not described in the specification filed or in the prior art at the time of filing.

7. In regards to the scope of enablement rejection of claims 1-10, 12 and 18-22, the rejection of record considers that applicant has not taught one skilled in the art how to make and use the claimed invention commensurate with the full scope of what is claimed, for proteins other than the full-length factor VIII, for example, as set forth in the prior Office actions of 05/06/2003 and 12/19/03.

Applicant's claim amendments filed 6/10/2004, with respect to the enablement of claims 1-10, 12 and 18-22 have been fully considered but are not found persuasive. Applicant's arguments do not address the above grounds of rejection. Specifically, applicant's amendments to the claims are addressed to the written description rejection as set forth in the prior Office action of 12/19/2003.

Therefore, the rejections of record under 35 U.S.C 112 in regards to both written description and enablement, are maintained as they pertain to claims 1-10, 12 and 18-22.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

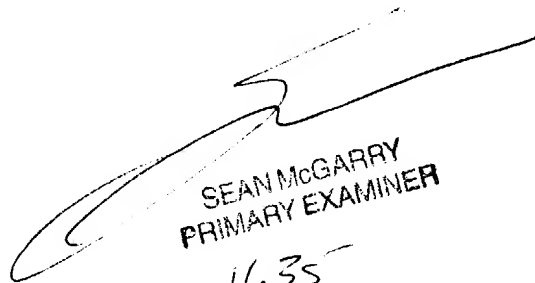
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

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problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba


SEAN MCGARRY
PRIMARY EXAMINER
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